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K962365

DSP Worldwide Snowden-Pencer Xenon Lightsource
510(k) Summary
(per 21 CFR 807.92)

1. Date of Preparation

June 18, 1996

2. Sponsor/Applicant

DSP Worldwide
Snowden-Pencer
5175 South Royal Atlanta Drive
Tucker, GA 30084

DSP Worldwide
600 Airport Road
Fall River, MA 02720

3. Contact Name

Timothy N. Thomas, Vice President, Regulatory Affairs and Quality Assurance
DSP Worldwide
Telephone: 508-677-6545

4. Device Name

Trade/Proprietary Name: Xenon Lightsource
Common/Usual Name: Xenon fiberoptic light source
Classification Name: Endoscopic accessory

5. Identification of the predicate or legally marketed device(s) to which equivalence is being claimed:

Karl Storz Xenon Light Source

K912365

6. Device Description

The DSP Worldwide Snowden-Pencer Xenon Lightsource is a fiberoptic illuminator for use in endoscopic surgical procedures. The device includes a Power Switch/Circuit Breaker, Light Guide receptacle which accepts the fiber optic cables (designed to accept ACMI cables with Storz, Olympus, and Wolf adapters also available), Lamp Usage Clock which indicates elapsed bulb usage (in hours), Light Intensity Control which allows illumination to be adjusted (clockwise to increase intensity and counterclockwise to decrease intensity), Light Intensity Indicator which provides a graphic representation of the level of light intensity, a Lamp Door on the side of the unit to provide access for replacement of the lamp module, a Cooling Fan to cool the Xenon bulb and the power supply of the unit. Detailed specifications for the Lightsource were provided.

7. Intended Use

The DSP Worldwide Snowden-Pencer Xenon Lightsource is intended for use as an accessory to fiberoptic endoscopes to provide illumination during endoscopic procedures.

8. Similarities in Technological Characteristics

The DSP Worldwide Snowden-Pencer Xenon Lightsource is substantially equivalent the Karl Storz Xenon Light Source and to other legally marketed xenon light sources in design characteristics, operational principles, and technological characteristics. Any difference between devices is minor and raises no new issues of safety and effectiveness.